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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/868,261 | 10/05/2001 | John P. McKearn | CU-2563 RJS | 7559 |

7590 08/21/2003

Mr. James M. Warner
Assistant General Counsel - Pharmacia Corportation
Global Patent Department
800 North Lindbergh Blvd.,
St. Louis, MO 63167

| EXAMINER |
|---|
| GOLDBERG, JEROME D |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1614 | 10 |

DATE MAILED: 08/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/868,261 | MCKEARN ET AL. | |
| | Examiner | Art Unit | |
| | Jerome D Goldberg | 1614 | |

*-- The MAILING DATE f this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *19 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-144* is/are pending in the application.

4a) Of the above claim(s) *1-140,142 and 143* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *141 and 144* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Claims 1-140, 142 and 143 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 9.

Applicants further elected the single enhanced combination of celecoxib and an alanine compound with traversed in paper no. 9, pages 24 and 25. In view of applicants' remarks all the alanine compounds will be examined with the celecoxib. The restriction requirement is herein modified and made final.

Claim 144 will be examined as it reads on the elected invention as herein modified.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 141 and 144 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Seifert et al. publication (WO 98/16227) of record taken with the Cunningham et al. patent.

The instant application has an effective date of December 23, 1998 while the Seifert et al. publication has an effective date of April 23, 1998 and the Cunningham et al. patent has an effective date of March 4, 1998. The Seifert et al. Publication teaches applicants' celecoxib for treating neoplasia in a subject (see claims 1, 9, 12 and 18 pages 33, 36, and 47) either alone or with other anticancer agents.

The Cunningham et al. patent teaches applicants' alanine compound for treating cancer (see claim 3, col.64, line 25) with other anticancer agents. The reference does not teach the claimed combination together. Accordingly, one skilled in this art would find ample motivation from the prior art supra to combine the well known anti-cancer agents together where the results obtained thereby are no more than the additive effects of the anti-cancer agents. The specification fails to show the elected combination together produces greater than the additive effects.

Claim 141 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific neoplasia disorder disclosed, does not reasonably provide enablement for the term"neoplasia disorder". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The term "neoplasia disorders" in claim 141 lacks clear exemplary support in the specification as filed, connected, to use the invention commensurate in scope with

these claims. The term "neoplasm" in claim 1 and 2 lacks clear exemplary support in the specification as filed.

Enablement is considered in view of the Wands factors (MPEP 2164.01 (a). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, predictability of the prior art, state of the prior art and the amount of experimentation necessary all of the wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the invention: claim 141 is drawn to treating neoplasms broadly with celecoxib and an alanine compound in a mammal.

Breath of the claims : the complex nature of the claim greatly exacerbated by breath of the claims. The claims encompass treating neoplasms broadly in a mammal.

Guidance of the specification :

The guidance given by the specification as to how one would one would administer the claimed compounds to a subject in order to treating neoplasms broadly. The guidance provide by the specification is directed to specific cancer in a specific concentration of the claimed compounds.

Working examples: all the working examples provided by the specification are directed to specific cancers.

State of the art: while the state of the art is relatively high with regard to treatment of specific cancers, the state of the art with regard to treating cancer or neoplasms broadly is underdeveloped. In particular, there is no known anticancer agent which is effective

all cancers. The Carter et al reference clearly teaches that for the forty known anticancer agents, none are effective against all cancers. (see pages 362-365 of Carter et al reference).

Predictability of the art: the lack of significant guidance from the specification or prior art with regard to the actual treatment of all cancers or neoplasms in a mammal including humans subject with the claimed compounds makes practing the claimed invention unpredictable.

The quantity of experimentation necessary:

Applicants fail to provide guidance and information to allow the skilled artisan to ascertain which particular type of cancer the claimed anticancer agent is effective against without undue experimentation. The limited disclosure of several cancer is noted but will not support all cancers being claimed. The Carter et al reference shows data on twenty-three types of cancer. Applicants should at least test these types of cancer with the claimed anticancer agent.

The Carter et al. Reference further teaches what is needed for employing an in vetro system to be useful in a clinical application (see page 342, table 1).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner J. D. Goldberg whose telephone number is (703) 308-4606. The examiner can normally be reached on Monday-Thursday 9:00 A.M - 3:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Goldberg/tgd
August 14, 2003

JEROME D. GOLDBERG
PRIMARY EXAMINER